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Signature

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

SERGEI ZOLOTUKHIN BARRY J. BYRNE NICHOLAS MUZYCZKA

Serial No.: Unknown

Filed: Concurrently Herewith

For: METHOD OF PREPARING

RECOMBINANT ADENO-ASSOCIATED

VIRUS COMPOSITIONS

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: 4300.007897

Customer No.: 23720

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed within three months of the

filing date of this patent application or prior to the receipt of a first Official Action reflecting an

examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R

§ 1.97(b). No fees are believed to be due in connection with the filing of this Information

Disclosure Statement; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed

necessary for any reason relating to these materials, the Director is hereby authorized to deduct

said fees from Williams, Morgan & Amerson, P.C., Deposit Account No. 50-0786/4300.007897.

This application is a continuation application of Serial No. 09/621,475, filed July 21,

2000 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule

37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously

cited by or submitted to the Patent and Trademark Office in prior application Serial No.

09/621,475.

Applicants respectfully request that the listed documents be made of record in the present

case.

Respectfully submitted,

WILLIAMS, MORGAN & AMERSON

CUSTOMER NO. 23720

Date: December 9, 2003

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AGENT FOR APPLICANTS

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Form PTO-1449 (modified)		Atty. Docket No. 4300.007897	Serial No. Unknown	
List of Patents and Publications for Applicant's		Applicants		
Information Disclosure Statement		Sergei Zolotukhin, Barry J. Byrne and Nicholas Muzyczka		
(Use several sheets if necessary)		Filing Date: Concurrently Herew	Group: ith Unknown	
U.S. Patent Documents	Foreign I	Patent Documents	Other Art	
See Page 1	See Page 1		See Pages 1-3	

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,139,941	8-18-92	Muzyczka et al.	435	172.3	
	A2	5,646,034	7-08-97	Leavitt et al.	435	325	
	A3	5,658,776	8-19-97	Flotte et al.	435	172.3	
	A4	5,681,731	10-28-97	Lebkowski et al.			

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	В1	WO 93/24641	12-1993	PCT	-		
	B2	WO 96/39495	12-1996	PCT	-		
	В3	WO 97/08298	03-1997	PCT			
	B4	WO 98/00524	01-1998	PCT			

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Anderson and Grinsted, "A new method for the purification of human motile spermatozoa applying density-gradient centrifugation: Polysucrose media compared to percoll media," J. Assis. Reprod. Genet., 14:624-28, 1997.
	C2	Bartlett and Samulski, "Fluorescent viral vectors: A new technique for the pharmacological analysis of gene therapy," <i>Nature Med.</i> , 4:635-37, 1998.
	C3	Basi and Rebois, "Rate zonal sedimentation of proteins in one hour or less," <i>Anal. Biochem.</i> , 251:103-09, 1997.
	C4	Cartwright <i>et al.</i> , "Investigation of the role of lipids in the assembly of very low density lipoproteins in rabbit hepatocytes," <i>J. Lipid Res.</i> , 38:531-45, 1997.

EXAMINER: DATE CONSIDERED:		· · · · · · · · · · · · · · · · · · ·
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See Page 1	See Page 1		See Pages 1-3	

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C5 ⁻	Chiorini et al., "High-efficiency transfer of the T cell co-stimulatory molecule B7-2 to lymphoid cells using high-titer recombinant adeno-associated virus vectors," <i>Hum. Gene Ther.</i> , 6:1531-41, 1995.
	C6	Clark et al., "Cell lines for the production of recombinant Adeno-associated virus," Hum. Gene Ther., 6:1329-41, 1995.
	C7	Clark et al., "Highly purified recombinant adeno-associated virus vectors are biologically active and free of detectable helper and wild-type viruses," Hum. Gene Ther., 10:1031-39, 1999.
	C8	Conway et al., "Recombinant Adeno-associated virus Type 2 replication and packaging is entirely supported by a Herpes Simplex virus Type 1 amplicon expressing rep and cap," J. Virol., 71:8780-89, 1997.
	C9	Dracopoli, "Current Protocols in Human Genetics," John Wiley & Sons, Inc., Vol. 10, pp. 12.1.1-12.1.24, 1994-1998.
	C10	Ferrari et al., "New developments in the generation of Ad-free, high-titer rAAV gene therapy vectors," Nature Med., 3:1295-97, 1997.
	C11	Graham et al., "A novel method for the rapid separation of plasma lipoproteins using self-generating gradients of iodixanol," Atherosclerosis, 124:125-35, 1996.
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	C13	Hermans et al., "Purification of Higher Titer Adeno-Associated Virus Vectors for Gene Delivery in the Brain," Graduate School for Neurosciences, Netherlands Institute for Brain Research, Amsterdam, the Netherlands.
	C14	Hermonat and Muzyczka, "Use of adeno-associated virus as a mammalian DNA cloning vector: transduction of neomycin resistance into mammalian tissue culture cells," <i>Proc. Natl. Acad. Sci. USA</i> , 81:6466-70, 1984.
	C15	Herold et al., "Identification of structural features of heparin required for inhibition of Herpes Simplex virus Type 1 binding," Virol., 206:1108-16, 1995.
·	C16	Inoue and Russell, "Packaging cells based on inducible gene amplification for the production of adeno-associated virus vectors," <i>J Virol.</i> , 72:7024-31, 1998.

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See Page 1	Se	ee Page 1	See Pages 1-3	

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	· C17	Klein, "Neuron-specific transduction in the rat septohippocampal or nigrostriatal pathway by recombinant adeno-associated virus vectors," <i>Exper. Neurol.</i> , 150:183-94, 1998.
	C18	Lewin <i>et al.</i> , "Ribozyme rescue of photoreceptor cells in a transgenic rat model of autosomal dominant retinitis pigmentosa," <i>Nat. Med.</i> , 4:967-71, 1998.
	.C19	Li et al., "Role for highly regulated rep gene expression in adeno-associated virus vector production," J. Virol., 71:5236-43, 1997.
	C20	Maxwell et al., "Improved production of recombinant AAV by transient transfection of NB324K cells using electroporation," J. Virol. Methods, 63:129-36, 1997.
	C21	Neyts et al., "Sulfated polymers inhibit the interaction of human cytomegalovirus with cell surface heparan sulfate," Virology, 189:48-58, 1992.
•	C22	Peel, "Efficient transduction of green fluorescent protein in spinal cord neurons using adenoassociated virus vectors containing cell type-specific promoters," <i>Gene Ther.</i> , 4:16-24, 1997.
	C23	Salvetti., "Factors influencing recombinant adeno-associated virus production," <i>Hum. Gene Ther.</i> , 9:695-706, 1998.
	C24	Sasagawa et al., "Synthesis and assembly of virus-like particles of human papillomaviruses type 6 and type 16 in fission yeast Scizosaccharomyces pombe," Virology, 206:126-35, 1995.
	C25	Snyder et al., "Production of recombinant adeno-associated viral vectors," In: Current Protocols in Human Genetics (eds. Dracopoli et al.), John Wiley, New York, 1996.
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	C29	Xiao et al., "Production of high-titer recombinant adeno-associated virus vectors in the absence of helper Adenovirus," J. Virol., 72:2224-32, 1998.
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